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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,862	01/30/2002	Michel Gau	HOE-676	6870

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/060,862

Applicant(s)

GAU, MICHEL

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/9/04 and 3/19/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12, 17 and 19-24 is/are rejected.
- 7) ☒ Claim(s) 13-16 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed February 9, 2004 have been fully considered but they are not persuasive.

Applicant has argued that Baumgartner (US 5,755,797) discloses bodies that are elastically deformable, and not rigid non-oxidizing. The examiner disagrees. Baumgartner's bodies 7, are disclosed to be solids, which have some rigidity (col.2, lines 13-15), and permanent dimensions (col.2, lines 3-4), and may even be made of metal (col.2, lines 57-59).

Applicant has argued that Baumgartner (US 5,320,644) is directed to a one piece, whole disc prosthesis, not a nucleus prosthesis. The examiner disagrees. Baumgartner's prosthesis is capable of being placed in the nucleus. Also, applicant has not claimed that the spherical body be a separate piece from the cage, therefore, the cage makes up the outside portion of the implant and the substantially spherical bodies make up the inner zone 9, and the bodies are within the cage. And, since the entire piece is rotatable, the substantially spherical zone 9 rotates along with the piece.

Applicant has argued that Ahrens Uwe (DE 19527975) does not disclose a substantially planar prosthesis, however, claims 10 and 20 do not claim a planar prosthesis.

Applicant has argued that Bristol-Myers Squibb (EP 0 577 179 A1) does not disclose a substantially spherical body that rotates in all directions, but only in one direction. The examiner disagrees. The examiner does not even claim a body rotatable in all direction, only two directions is claimed. Also, the 179' reference discloses a body that rotates in two directions, clockwise and counter clockwise about the cage.

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The examiner's position and further explanation is believed to be adequately described below.

Specification

It is noted to the applicant that although receipt of a statement acknowledging a substitute specification being attached was found, the actual substitute specification was not.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 11, 19, 20, 21, 22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (USPN 5,755,797, cited by applicant in IDS). Referring to claims 10 and 23, Baumgartner discloses an intervertebral nucleus prosthesis (col.1, lines 10-13) consisting of at least one substantially spherical body or ball (7) movable in two directions of a plane made of a rigid, non-oxidizing, biocompatible material (control rigidity by use of solid members, col.2, lines 13-15; permanently dimensionally stable, col.2, lines 1-4; support members 7 may be metal, col.2, lines 57-59), with a diameter adapted to a biological nucleus, the spherical body being mounted non-displaceably but freely rotatably about its center (col.2, lines 5-9) in a cage (10, 20) and protruding at both opposite sides of the cage in the form of spherical caps (fig.6).

Referring to claim 11, Baumgartner discloses a cage (10, 20) that is substantially planar, is curved in the plane and substantially symmetrical to a transverse plane (fig.6).

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Referring to claim 19, Baumgartner discloses a cage (10, 20) consisting of a single component or several components combined with bodies (7), having a volume like the volume of the biological nucleus, allowing self-positioning of the prosthesis (fig. 1, 2).

Referring to claim 20, Baumgartner discloses a spherical cap having a height *approximately* one tenth of a diameter of the spherical body (diameters may vary, col.4, lines 1-8; see figure 6).

Referring to claim 21 and 22, Baumgartner discloses a method for implanting an intervertebral nucleus (col.1, lines 10-15) for insertion of the prosthesis by making an incision endoscopically in the annulus (4) between two vertebral bodies (fig. 1, 3), providing an opening (30) large enough to remove and replace the nucleus (col.1, lines 50-54), and closing the opening (col.4, lines 37-39), wherein the opening may be closed with a suture (11, even though Baumgartner does not explicitly disclose a suture used to close the opening, it is so well known in the art and is obvious if not inherent to use a suture to close any tissue openings in the body).

Claims 10, 11, 12, 17, 19, 20, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (USPN 5,320,644). See figures 8, 9, and respective portions of the specification. Referring to claims 10, 23, and 24, Baumgartner discloses an intervertebral nucleus prosthesis (1) consisting of at least one substantially spherical body or ball (9, a portion of 1; see figures 8, 9) movable in two directions of a plane (movable by rotation clockwise and counter clockwise) made of a rigid, non-oxidizing, biocompatible material that is non-deformable (titanium, col.2, lines 13-14; col.3, lines 1-2), with a diameter adapted to a biological nucleus, the spherical body being mounted non-displaceably but freely rotatably about its center

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(col.3, lines 29-32, even though the implant is rotating as one piece, the sphere still does rotate about its center, it just rotates as a whole-it is noted that the applicant has only claimed rotation of the body, the applicant has not claimed rotation of the body within or about the cage) in a cage (volume of 1 outside of volume 9) and protruding at both opposite sides in the form of a spherical cap from the cage (fig.8).

Referring to claim 11, Baumgartner discloses a cage that is substantially planer, and is curved in a plane and symmetrical to a transverse plane (fig.8).

Referring to claim 12, Baumgartner discloses a cage with an isosceles trapezoid shape having a narrow and wide side (fig.9), facilitating displacement in the disc plane and preventing substantial rotation of the prosthesis about its center (col.3, lines 20-32).

Referring to claim 17, Baumgartner discloses a cage with an isosceles trapezoid shape (fig.9) and holds several bodies (9; fig.9) that touch and are located at both sides of the cage at corners of an isosceles triangle.

Referring to claim 19, Baumgartner discloses a cage consisting of a single component or several components combined with bodies, having a volume like the volume of the biological nucleus, allowing self-positioning of the prosthesis.

Referring to claim 20, Baumgartner discloses a spherical cap having a height *approximately* one tenth of a diameter of the spherical body (fig.8).

Claims 10 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahrens Uwe (DE 19527975, cited by applicant in IDS). Referring to claim 10, Ahrens Uwe discloses an intervertebral nucleus prosthesis (fig.1, 2, total replacement joints for knee, hip, shoulder, or

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other joints, wherein the vertebral nucleus is a well known joint, abstract, col.1, lines 1-7) consisting of at least one substantially spherical body or ball (1) movable in two directions of a plane made of a rigid, non-oxidizing, biocompatible material, with a diameter adapted to a biological nucleus, the spherical body being mounted non-displaceably but freely rotatably about its center (col.3, lines 1-2) in a cage (2, 3) and protruding at both opposite sides in the form of a spherical cap from the cage (fig.1, 2).

Referring to claim 20, Ahrens Uwe discloses a spherical cap (top and bottom portions of 1) having a height *approximately* one tenth of a diameter of the spherical body (fig.1, 2).

Claims 10, 11, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bristol-Myers Squibb Company (EP 0577179 A1, cited by applicant in IDS). Referring to claims 10, 23, and 24, Bristol-Myers Squibb discloses an intervertebral nucleus prosthesis (1) consisting of at least one substantially spherical body or ball (2) movable in two directions of a plane made of a rigid, non-oxidizing, biocompatible material that's non-deformable (col.1, lines 4-6), with a diameter adapted to a biological nucleus, the spherical body being mounted non-displaceably but freely rotatably about its center (fig.3 has shown an embodiment with flattened portions, which prevent rotation, col.2, lines 19-27, however since the embodiments in fig.1 and 2 are spherical, they will inherently rotate) in a cage (6) and protruding at both opposite sides in the form of a spherical cap from the cage (fig.1).

Referring to claim 11, Bristol Myers Squibb discloses a cage that is substantially planar and is curved in a plane and symmetrical to a transverse plane (fig.1, 2).

Allowable Subject Matter

Claims 13-16 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

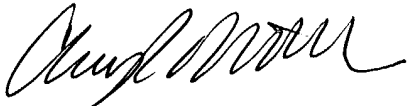
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

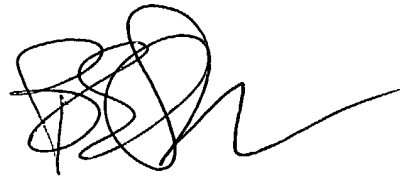
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER